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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/802,425

03/17/2004

Bonnie L. Bassler

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3998

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7590

11/26/2008

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EXAMINER

JOIKE, MICHELE K

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

11/26/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/802,425	<b>Applicant(s)</b> BASSLER ET AL.	
	<b>Examiner</b> MICHELE K. JOIKE	<b>Art Unit</b> 1636	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-36, 39-48, 99 and 100 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 99 and 100 is/are allowed.
- 6) ☒ Claim(s) 1, 3-36, 39, 40 and 42-48 is/are rejected.
- 7) ☒ Claim(s) 2, 41 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on August 11, 2008 has been entered.

Claims 1-36, 39-48 and 99-100 are pending in the instant application and are examined. Any rejection of record in the previous Office Action, mailed August 8, 2008 that is not addressed in this action has been withdrawn.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-36, 39-40 and 42-48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support for excluding homoserine lactone autoinducer-2s.

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While there is support for other autoinducer-2s; there is no support for “non-homoserine lactone auto-inducer-2.” This is a NEW MATTER rejection.

Claims 1, 3-36, 39-40 and 42-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for LuxS genes encoding autoinducer-2 and 4-hydroxy-5-methyl-2H-furan-3-one, does not reasonably provide enablement for non-homoserine lactone autoinducer-2s. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

*Nature of the invention:* The nature of the invention is a method for identifying a compound that regulates the activity of a non-homoserine lactone autoinducer-2.

*Breadth of the claims:* The claims are broad in that any autoinducer-2 that is a non-homoserine lactone (HSL) autoinducer-2 is included, even molecules that have not been discovered.

*Guidance of the specification:* The specification does not mention the term "non-homoserine lactone" autoinducer-2. It does disclose LuxS genes encoding an autoinducer-2 and the analog, 4-hydroxy-5-methyl-2H-furan-3-one, but does not disclose any other non-HSLs. The working example is limited to the contacting autoinducer-2 (4-dihydroxy-5-methyl-2H-furan-3-one) with a compound that regulates the activity of the autoinducer-2 and detecting an autoinducer-associated bacterial biomarker.

*Predictability and state of the art:* Non-homoserine lactone is not a common term on the art. While HSLs are common, non-HSLs are not. Turovskiy et al (Adv Appl Microbiol. 62: 191–234, 2007) only discuss LuxS encoded autoinducer-2 (AI-2), and state that it is an elusive molecule and that even the function of quorum sensing is not clear. Furthermore, they report that Bassler et al have discovered new quorum-sensing regulated genes, so there may be more non-HSLs autoinducer-2s than previously reported. The field is still growing, and it is difficult to predict what non-HSLs will be discovered.

*Amount of experimentation necessary:* Non-homoserine lactone autoinducer-2 is a broad term. Even autoinducer-2 is used broadly. For example, 4-hydroxy-5-methyl-2H-furan-3-one is disclosed as an analog of autoinducer-2 in the specification, but is claimed as an autoinducer-2 in claims 2 and 41. There is no guidance as to what activity or function an autoinducer-2 has to have to be a non-homoserine lactone autoinducer-2. As there does not seem to be any common properties to non-homoserine lactone autoinducer-2s, other than that they are non-homoserine lactone, it would cause undue

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experimentation to identify potential molecules and test if the molecules can act as autoinducer-2s.

***Allowable Subject Matter***

Claims 2 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 99 and 100 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELE K. JOIKE whose telephone number is (571)272-5915. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

Michele K Joike  
Examiner  
Art Unit 1636